October 1, 2002

U.S. Environmental Protection Agency

Office of Pesticide Programs

Electronic Data Submission and Review

Preparation and In-Processing of Studies Submitted in PDF

This document describes the process by which:

- Registrants prepare an electronic submission to OPP,
- OPP in-processes the submission including PRN 86-5 compliance review.

Assumptions:

Electronic submissions must be created in Adobe® Portable Document Format (PDF) Version 1.4. Adobe® Acrobat® Version 5 is the tool OPP is using for review purposes. See 'Specifications for Creating a PDF Version of Study Reports' for full details.

Three PDF creation techniques are possible and an electronic submission may comprise any combination of the three. From 'ideal' to 'ok', they are:

1. Create PDF directly from electronic source (word processing file, etc.),

2. Scan paper copy of study report. Process through optical character recognition (OCR) software such as Adobe® Acrobat® Capture®, ABBYY® Fine Reader®, or ScanSoft® OmniPage® Pro to create a text PDF providing text extraction and indexing capabilities.

3. Create a PDF that is scanned image of paper document.
    - *This option produces a graphic-only PDF file and does not allow for required text manipulation. It should only be used for photographs, chromatograms, and any other graphic-based data where use of OCR is impractical.*

The following key points should be considered prior to submitting studies electronically:

- A full submission may be submitted in PDF or only parts of a submission may be submitted in PDF with the balance submitted as paper only.
- Registrants should notify OPP prior to making an electronic submission. Contact —Teresa Downs, Information Services Branch (ISB), 703-305-5363 or Bob Schultz, ISB, 703-308-8186.
- The official version of the submission remains the paper copies of the studies. When an electronic submission is planned, ONLY TWO PAPER COPIES ARE REQUIRED.
- All submissions – whether in paper or electronic format – must conform to PRN 86-5. Electronic submissions that are not in compliance with 86-5 will be rejected.
- At this time, electronic submissions may **NOT** include FIFRA Confidential Business Information (CBI).
- The submission medium is compact disk (CD) only. The agency is not prepared to receive and secure submissions via the agency network.

In some cases a registrant may need to:

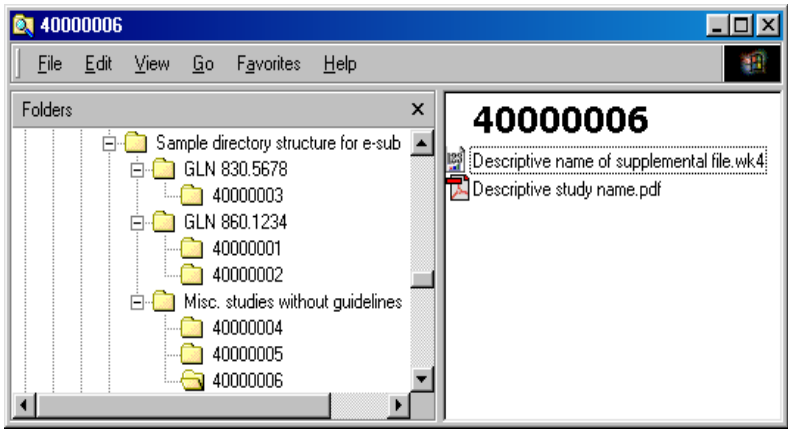
- submit a revised study for the purpose of correcting errors in the original report,
- provide supplementary information such as historical control data for a study,
- submit one or more additional studies in support of the regulatory action.

In these circumstances, the registrant has the option of providing an electronic version of these additional data. He or she would prepare and submit two paper copies of the additional data in PRN 86-5 format. After being notified of the MRIDs assigned to the paper submission, the registrant would submit an electronic version on CD.

What follows are the steps that will be performed by ISB and the registrant.

1. Registrant decides to make an electronic data submission.	See 'Specifications for Creating a PDF Version of Study Reports'. Registrant calls ISB — (Teresa Downs 703-305-5363 or Bob Schultz 703-308-8186)
2. Registrant submits two paper copies of submission. * When a submission will consist of some electronic studies but not all, only 2 paper copies are still required of all studies. **Clearly indicate on the transmittal document which specific studies will be submitted electronically.**	Registrant clearly indicates in transmittal letter intention to submit an electronic version of some/all studies. The first line of the address will read: **Document Processing Desk (E-SUB)** Send via courier to OPP's physical location at: **U.S. EPA – Office of Pesticide Programs** **Room 266A** **1921 Jefferson Davis Hwy.** **Arlington, VA 22202** USPS delivery is not recommended at this time due to delays caused by the sterilization of all incoming mail.

3. ISB in-processes the two paper copies.	ISB performs routine in-processing tasks on paper versions of studies: pin-punching, PRN 86-5 compliance review, etc. If one or more studies fail the review, ISB notifies the submitter and works with them to correct the formatting errors. Once the formatting issues have been resolved, if any, ISB notifies the submitter of the MRIDs assigned to the studies.

4. Registrant prepares electronic submission using the assigned MRIDs as part of the specified file structure on the CD and naming convention for each study.
 	
* When referencing guidelines, use whichever guideline set (old vs. harmonized) is appropriate for the study.
	The directories/sub-directories are as follows...
	For each study:
	`Guideline number` *(of first study)*
	`└MRID`
	`└MRID_Descriptive_name.pdf`
	
	Examples of suitable names are:
	`45612301 chronic rat feeding.pdf`
	`45612302 residue apples.pdf`
	`45612303 metabolism aerobic water-sediment.pdf`
	
	If supplemental files are included with the study:
	`Guideline number` *(of first study)*
	`└ MRID`
	`└Descriptive_name.xxx`
	where the extension .xxx is appropriate for the type of file.
	
	 

5. Registrant prepares transmittal letter.	The transmittal letter describes the contents of the CD. The transmittal letter should be part of the PDF files and will provide a table of contents to the PDF studies using Bookmarks.

6. Registrant prepares certification that electronic version and paper version of studies contain the same information.	See the 'Certification with Respect to Data Integrity'. A paper version of the certification must be submitted and a PDF version of the certification must be included on the CD.
7. Registrant prepares CD with label.	Label on the CD and jewel box should provide the following information: Name of registrant and EPA Company Number, Name of chemical, Brief description of application.
8. Registrant flags the electronic submission as such and sends to ISB's Document Processing Desk.	The first line of the address will read: **Document Processing Desk (E-SUB)** Send via courier to OPP's physical location at: **U.S. EPA – Office of Pesticide Programs** **Room 266A** **1921 Jefferson Davis Hwy.** **Arlington, VA 22202** USPS delivery is not recommended at this time due to delays caused by the sterilization of all incoming mail.
9. ISB in-processes CD.	ISB opens the files on the CD, scans for viruses, then ensures that– • File structures and naming conventions are correct, • Electronic files match transmittal letter, • *Certification with Respect to Data Integrity* covers all electronic studies.
10. If CD/study formats do not conform to guidance, ISB contacts the registrant.	If any corrections are needed, registrant will be required to re-cut and re-submit entire CD. ISB will not alter a registrant submission.